# General

## Guideline Title

Afatinib for treating epidermal growth factor receptor mutation-positive locally advanced or metastatic non-small-cell lung cancer.

## Bibliographic Source(s)

National Institute for Health and Care Excellence. Afatinib for treating epidermal growth factor receptor mutation-positive locally advanced or metastatic non-small-cell lung cancer. London (UK): National Institute for Health and Care Excellence; 2014 Apr. 40 p. (Technology appraisal guidance; no. 310).

## Guideline Status

This is the current release of the guideline.

This guideline meets NGC's 2013 (revised) inclusion criteria.

# Recommendations

## Major Recommendations

Afatinib is recommended as an option, within its marketing authorisation, for treating adults with locally advanced or metastatic non-small-cell lung cancer only if:

- The tumour tests positive for the epidermal growth factor receptor-tyrosine kinase (EGFR-TK) mutation and
- The person has not previously had an EGFR-TK inhibitor and
- The manufacturer provides afatinib with the discount agreed in the patient access scheme.

## Clinical Algorithm(s)

None provided

# Scope

## Disease/Condition(s)

Epidermal growth factor receptor mutation-positive locally advanced or metastatic non-small-cell lung cancer

## Guideline Category

Assessment of Therapeutic Effectiveness

Treatment

## Clinical Specialty

Internal Medicine

Oncology

Pulmonary Medicine

## Intended Users

Advanced Practice Nurses

Physician Assistants

Physicians

## Guideline Objective(s)

To assess the clinical effectiveness and cost-effectiveness of afatinib for treating epidermal growth factor receptor mutation-positive locally advanced or metastatic non-small-cell lung cancer

## Target Population

Epidermal growth factor receptor-tyrosine kinase inhibitor (EGFR-TKI)-naïve adult patients with locally advanced or metastatic non-small-cell lung cancer

## Interventions and Practices Considered

Afatinib

## Major Outcomes Considered

- Clinical effectiveness
  - Overall survival
  - Progression-free survival
  - Response rates
  - Adverse effects of treatment
  - Health-related quality of life
- Cost-effectiveness

# Methodology

## Methods Used to Collect/Select the Evid

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Searches of Electronic Databases

# Description of Methods Used to Collect/Select the Evidence

Note from the National Guideline Clearinghouse (NGC): The National Institute for Health and Care Excellence (NICE) commissioned an independent academic centre to perform an assessment of the manufacturer's submission on the technology considered in this appraisal and prepare an Evidence Review Group (ERG) report. The ERG report for this technology appraisal was prepared by Liverpool Reviews & Implementation Group (LRiG) (see the "Availability of Companion Documents" field).

Clinical Effectiveness

Critique of the Methods of Reviews

*Searches*

Sections 6.1 and 10.2 of the manufacturer's submission (MS) describe the search strategies employed for the systematic review (direct evidence) and mixed treatment comparison (MTC) (indirect evidence), respectively.

The following databases were searched on 6 March 2012 spanning the period from 2002 to 2012:

1. EMBASE (via the OVID platform)
2. Medline & Medline In-Process (via the OVID platform)
3. Cochrane Library (via the InterScience platform) - includes:
    - Cochrane Database of Systematic Reviews (Cochrane Reviews)
    - Database of Abstracts of Reviews of Effects (Other Reviews)
    - Cochrane Central Register of Controlled Trials (Clinical Trials)
    - Cochrane Methodology Register (Methods Studies)
    - Health Technology Assessment Database (Technology Assessments)
    - NHS Economic Evaluation Database (Economic Evaluations)

While the manufacturer has searched key databases and documented search strategies adequately, the ERG notes that no search for conference abstracts from other sources (such as specific cancer conferences) was undertaken. Wider searching may have resulted in additional trials being identified although the ERG accepts that the usefulness of data from these trials may be limited.

For all databases, a combination of free text and index terms were used, the intention being to limit the search to randomised controlled trials (RCTs) of patients with non-small-cell lung cancer (NSCLC) published in English after 2002. It is not clear from the MS why searches were limited to publications from 2002 onwards. Searches included 'any of the interventions licensed for the treatment of locally advanced or metastatic NSCLC'. Free text words for both generic and brand names of drugs were used. The ERG notes that search terms included a greater number of drugs than specified in the final scope issued by NICE. The ERG notes that the searches were conducted in March 2012 and have not been updated subsequently. The manufacturer's rationale for not updating the searches was that no major trials have been published since (other than those relating to afatinib identified by the manufacturer's clinical experts). While accepting that clinical experts may be aware of major trials, the ERG believes that searches should have been updated in order to minimise risk of retrieval bias. The manufacturer conducted a supplementary search using the terms 'EGFR mutation NSCLC' and the same databases. This search aimed to identify systematic reviews of studies of epidermal growth factor receptor (EGFR)-positive patients published after March 2012 and, according to the manufacturer's response to the ERG as part of the clarification process, was carried out on 6 August 2013. No further details were available for this search.

In summary, despite some limitations as outlined above, the ERG considers that the search strategies employed by the manufacturer were appropriate and sufficiently comprehensive to identify relevant studies.

Inclusion Criteria

The inclusion criteria used in the systematic reviews is summarised in Table 4 of the ERG report. The ERG notes that in addition to the eligibility criteria specified in the tables, studies were also limited to the first-line setting (see the "Availability of Companion Documents" field).

Cost-effectiveness

ERG Comment on Manufacturer's Review of Cost-effectiveness Evidence

*Objective of the Manufacturer's Cost-effectiveness Review*

EMBASE, Medline & Medline In-process, and EconLit were searched via the OVID platform whilst the Cochrane Library was searched via the InterScience platform. The time horizon for the search was limited to studies published from 2002-2012 (inclusive).

*Inclusion/Exclusion Criteria Used in the Study Selection*

The inclusion criteria used in the study selection are presented in Table 23 of the ERG report (see the "Availability of Companion Documents" field).

## Number of Source Documents

Clinical Effectiveness

- The systematic review identified two studies (both phase III trials; LUX-Lung 3 and LUX-Lung 6) comparing afatinib with chemotherapy.
- Data from a single-arm study, LUX-Lung 2 was also considered relevant to the decision problem.

Cost-effectiveness

The search of the literature yielded 3710 citations, all records were excluded.

## Methods Used to Assess the Quality and Strength of the Evidence

Expert Consensus

## Rating Scheme for the Strength of the Evidence

Not applicable

## Methods Used to Analyze the Evidence

Systematic Review with Evidence Tables

## Description of the Methods Used to Analyze the Evidence

Note from the National Guideline Clearinghouse (NGC): The National Institute for Health and Care Excellence (NICE) commissioned an independent academic centre to perform an assessment of the manufacturer's submission on the technology considered in this appraisal and prepare an Evidence Review Group (ERG) report. The ERG report for this technology appraisal was prepared by Liverpool Reviews & Implementation Group (LRiG) (see the "Availability of Companion Documents" field).

Clinical Effectiveness

Critique of the Methods of Review(s)

*Quality Assessment*

The manufacturer conducted a quality assessment of three studies of afatinib, two randomised controlled trials (RCTs) (LUX-Lung 3, LUX-Lung 6) and a single-arm phase II study (LUX-Lung 2) and all studies included in a mixed treatment comparison (MTC). This included elements of the tool for assessing risk of bias, as recommended by the Cochrane Collaboration. The ERG agrees this is an appropriate tool for assessing quality of RCTs. No other trials were included in the systematic review.

*Evidence Synthesis*

Two trials (LUX-Lung 3 and LUX-Lung 6) were identified by the systematic review, both with different comparators (pemetrexed/cisplatin and gemcitabine/cisplatin). If it is assumed that these two comparators are of equal efficacy, then it may have been appropriate to have conducted a meta-analysis. However, as noted in Section 2.2 of the ERG report, there is evidence that pemetrexed/cisplatin is superior to gemcitabine/cisplatin

in non-squamous non-small-cell lung cancer (NSCLC). Therefore the findings were appropriately presented narratively. Thus in order to compare afatinib to comparators of interest (erlotinib and gefitinib) it was necessary to conduct a MTC. See Section 4.3 of the ERG report for more information, including the ERG's critique of the manufacturer's MTC (see the "Availability of Companion Documents" field).

Critique of Direct Evidence of Clinical Effectiveness Evidence

*Identified Studies in the Systematic Review*

The systematic review identified two studies (both phase III trials; LUX-Lung 3 and LUX-Lung 6 comparing afatinib with chemotherapy. In addition to evidence from these two RCTs, data from a single-arm study, LUX-Lung 2 was also considered relevant to the decision problem. The ERG is not aware of any additional completed studies of afatinib relevant to this appraisal although it is noted that there is an ongoing phase IIb trial comparing afatinib with gefitinib (LUX-Lung 7). This trial is enrolling 316 patients from Australia, Canada, Asia (China, Hong Kong, Singapore, South Korea, Taiwan) and Europe (France, Germany, Ireland, Norway, Spain, Sweden and the UK). The estimated study completion date for this trial is December 2014.

*Quality Assessment of the Trials Included in the Systematic Review*

The manufacturer conducted a quality assessment of the included studies. This included elements of the tool for assessing risk of bias, as recommended by the Cochrane Collaboration. LUX-Lung 3 and LUX-Lung 6 were deemed to be of good quality.

*Results of the Trials Included in the Systematic Review*

Progression-free survival (PFS) data for LUX-Lung 3 and LUX-Lung 6 are reproduced in Table 6 in the ERG report. The primary analysis in both trials was based on central independent assessments. Median PFS is reported to be similar for local and central independent assessment in LUX-Lung 3. However, in LUX-Lung 6 local assessment estimated the difference in median PFS time between afatinib and chemotherapy arms to be 8.18 months, considerably higher than the 5.42 months estimated by central independent assessment.

For LUX-Lung 3 and LUX-Lung 6 the manufacturer provides forest plots, pre-specified in the protocol, for key subgroup analyses of PFS based on central independent assessment. Subgroups include (but are not limited to) age, gender, ethnicity, types of epidermal growth factor receptor (EGFR) mutations and smoking status and are summarised in Appendix 22.1.3 of the ERG report. The findings of subgroup analysis are consistent with those of the PFS primary analysis.

In response to the ERG's request as part of the clarification process for findings to be presented for Asian and non-Asian patients, the manufacturer presented a subgroup analysis of local investigator assessed PFS in LUX-Lung 3 as summarised in Table 7 in the ERG report. This exploratory analysis suggests that Asian patients may have improved PFS compared with non-Asian patients.

Overall survival (OS) data presented by the manufacturer are not mature for either LUX-Lung 3 or LUX-Lung 6 as in neither trial, the planned number of events (deaths) to assess OS have not occurred. Most recent OS data for both trials are summarised in Table 8 in the ERG report.

*ERG Analysis of OS and PFS Data from LUX-Lung-3 Clinical Trial*

The ERG requested detailed information from the manufacturer of afatinib in the form of Kaplan-Meier survival analyses for OS, PFS and post-progression survival (PPS) distinguishing between two subgroups: those of Asian origin and those of non-Asian origin. The aim of this exercise was to determine whether there is evidence that the experience of patients in responding to treatment differed by ethnic origin, and whether alternative projective model formulations may represent more accurately the trial results than the Weibull functions employed by the manufacturer in the submitted model. The analysis was carried out for PFS and OS, but the number of patients and events in the PPS dataset proved to be inadequate for meaningful analysis.

The requested survival analyses involved use of the most recent data update, and a different censoring rule (censoring at time of data cut, not of last observation) to remove bias from informative censoring. It is important to note that origin (Asian vs non-Asian) is a stratification variable for this clinical trial, so that analyses using these subgroups should be free of biases inherent in post-hoc exploratory subgroup analyses.

Critique of Indirect Evidence of Clinical Effectiveness

*Methodological Approach to MTC*

The MTC used a Bayesian approach and was performed using the Markov chain Monte Carlo software package WinBUGs. This approach combines a prior probability distribution with a likelihood distribution. The prior distribution reflects a prior belief of the possible values of the pooled relative effects of the pooled effect. The likelihood distribution is based on observed data in different studies to obtain a posterior distribution of the pooled relative treatment effect. The manufacturer performed MTCs for three outcomes; PFS, OS and adverse effects. The

metrics used in the MTC for OS and PFS were log hazard ratios and standard error.

See Section 4 of the ERG report for more information on clinical effectiveness analysis (see the "Availability of Companion Documents" field).

Cost-effectiveness

Summary and Critique of Manufacturer's Submitted Economic Evaluation by the ERG

The model compares afatinib monotherapy with other tyrosine kinase inhibitors (TKIs) in a first-line setting. No comparison is made between afatinib and chemotherapy. No economic modelling been carried out to support the use of afatinib as a second-line treatment. However, the manufacturer reports that results from LUX-Lung 2 showed no significant difference in objective response rate in patients receiving afatinib as a first-line treatment (40/61 patients [66%]) and those receiving second-line treatment (39/68 [57%]; Odds ratio 0.71, 0.35 to 1.44). Although the manufacturer recognises that this trial was not powered to detect differences between the two groups they suggest that if afatinib is cost effective compared with gefitinib and erlotinib as a first-line treatment, and outcomes for first and second-line patients receiving afatinib are similar then, if afatinib were compared with gefitinib and erlotinib second-line incremental cost-effectiveness ratios (ICERs) would be similar. The manufacturer recognises that this would require the additional assumption that gefitinib and erlotinib were equally efficacious in second-line as in first-line.

Refer to the ERG report for additional information on the manufacturer's submitted economic evaluation (see the "Availability of Companion Documents" field).

## Methods Used to Formulate the Recommendations

Expert Consensus

## Description of Methods Used to Formulate the Recommendations

Considerations

Technology appraisal recommendations are based on a review of clinical and economic evidence.

Technology Appraisal Process

The National Institute for Health and Care Excellence (NICE) invites 'consultee' and 'commentator' organisations to take part in the appraisal process. Consultee organisations include national groups representing patients and carers, the bodies representing health professionals, and the manufacturers of the technology under review. Consultees are invited to submit evidence during the appraisal and to comment on the appraisal documents.

Commentator organisations include manufacturers of the products with which the technology is being compared, the National Health Service (NHS) Quality Improvement Scotland and research groups working in the area. They can comment on the evidence and other documents but are not asked to submit evidence themselves.

NICE then commissions an independent academic centre to review published evidence on the technology and prepare an 'assessment report'. Consultees and commentators are invited to comment on the report. The assessment report and the comments on it are then drawn together in a document called the evaluation report.

An independent Appraisal Committee then considers the evaluation report. It holds a meeting where it hears direct, spoken evidence from nominated clinical experts, patients and carers. The Committee uses all the evidence to make its first recommendations, in a document called the 'appraisal consultation document' (ACD). NICE sends all the consultees and commentators a copy of this document and posts it on the NICE Web site. Further comments are invited from everyone taking part.

When the Committee meets again it considers any comments submitted on the ACD; then it prepares its final recommendations in a document called the 'final appraisal determination' (FAD). This is submitted to NICE for approval.

Consultees have a chance to appeal against the final recommendations in the FAD. If there are no appeals, the final recommendations become the basis of the guidance that NICE issues.

Who Is on the Appraisal Committee?

NICE technology appraisal recommendations are prepared by an independent committee. This includes health professionals working in the NHS

and people who are familiar with the issues affecting patients and carers. Although the Appraisal Committee seeks the views of organisations representing health professionals, patients, carers, manufacturers and government, its advice is independent of any vested interests.

## Rating Scheme for the Strength of the Recommendations

Not applicable

## Cost Analysis

Summary of Appraisal Committee's Key Conclusions

Availability and Nature of Evidence

The manufacturer of afatinib submitted cost-effectiveness evidence as part of its submission, based on a mixed treatment comparison.

The Evidence Review Group (ERG) submitted an exploratory cost analysis and an exploratory economic analysis of afatinib compared with cisplatin in combination with pemetrexed, based on the trial data.

Uncertainties Around and Plausibility of Assumptions and Inputs in the Economic Model

The Committee concluded that methodological issues related to the assumption of proportional hazards, the extrapolation of progression-free survival and the population of the base-case model prevented the Committee from assessing the cost-effectiveness of afatinib compared with erlotinib and gefitinib based on the manufacturer's model. Therefore a most plausible incremental cost-effectiveness ratio (ICER) could not be estimated.

Incorporation of Health-Related Quality-of-Life Benefits and Utility Values. Have Any Potential Significant and Substantial Health-Related Benefits Been Identified That Were Not Included in the Economic Model, and How Have They Been Considered?

The Committee did not draw any specific conclusions about the health-related quality-of-life benefits and utility values.

Are There Specific Groups of People for Whom the Technology Is Particularly Cost Effective?

None were identified.

What Are the Key Drivers of Cost-effectiveness?

The main drivers of cost-effectiveness were: the mixed treatment comparison-based hazard ratios for progression-free and overall survival, the cost per month for the progression-free health state and the cost per month for the best supportive care period of the progressive disease health state.

Most Likely Cost-effectiveness Estimate (Given as an ICER)

A most plausible ICER could not be estimated.

The Committee concluded that on balance, based on all the evidence considered, afatinib is considered to be a reasonable alternative treatment option compared with erlotinib and gefitinib, in people with locally advanced or metastatic epidermal growth factor receptor (EGFR) mutation-positive non-small-cell lung cancer (NSCLC) that has not been previously treated with an EGFR tyrosine kinase inhibitor or chemotherapy.

## Method of Guideline Validation

External Peer Review

## Description of Method of Guideline Validation

Consultee organisations from the following groups were invited to comment on the draft scope, Assessment Report and the Appraisal Consultation Document (ACD) and were provided with the opportunity to appeal against the Final Appraisal Determination.

- Manufacturer/sponsors
- Professional/specialist and patient/carer groups
- Commentator organisations (without the right of appeal)

In addition, individuals selected from clinical expert and patient advocate nominations from the professional/specialist and patient/carer groups were also invited to comment on the ACD.

# Evidence Supporting the Recommendations

## Type of Evidence Supporting the Recommendations

The type of evidence supporting the recommendations is not specifically stated.

The Appraisal Committee considered clinical and cost-effectiveness evidence submitted by the manufacturer of afatinib and a review of this submission by the Evidence Review Group (ERG). The main clinical effectiveness evidence came from randomised controlled trials. For cost-effectiveness, the Appraisal Committee considered an economic model submitted by the manufacturer.

# Benefits/Harms of Implementing the Guideline Recommendations

## Potential Benefits

Appropriate use of afatinib for treating epidermal growth factor receptor mutation-positive locally advanced or metastatic non-small-cell lung cancer

## Potential Harms

The summary of product characteristics lists the following very common adverse reactions for afatinib: diarrhoea, rash/acne, blistering and dry skin conditions, pruritus, decreased appetite, nose bleed, stomatitis (inflammation in the mouth) and paronychia (nail infection). For full details of adverse reactions and contraindications, see the Summary of Product Characteristics.

# Contraindications

## Contraindications

For full details of contraindications, see the Summary of Product Characteristics.

# Qualifying Statements

## Qualifying Statements

- This guidance represents the views of the National Institute for Health and Care Excellence (NICE) and was arrived at after careful consideration of the evidence available. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement. However, the guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.
- Implementation of this guidance is the responsibility of local commissioners and/or providers. Commissioners and providers are reminded that it is their responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity and foster good relations. Nothing in this guidance should be interpreted in a way

that would be inconsistent with compliance with those duties.

# Implementation of the Guideline

## Description of Implementation Strategy

- Section 7(6) of the National Institute for Health and Care Excellence (NICE) (Constitution and Functions) and the Health and Social Care Information Centre (Functions) Regulations 2013 requires clinical commissioning groups, National Health Services (NHS) England and, with respect to their public health functions, local authorities to comply with the recommendations in this appraisal within 3 months of its date of publication.
- When NICE recommends a treatment 'as an option', the NHS must make sure it is available within the period set out in the paragraph above. This means that, if a patient has epidermal growth factor receptor mutation-positive locally advanced or metastatic non-small-cell lung cancer and the doctor responsible for their care thinks that afatinib is the right treatment, it should be available for use, in line with NICE's recommendations.
- The Department of Health and the manufacturer have agreed that afatinib will be available to the NHS with a patient access scheme which makes afatinib available with a discount. The size of the discount is commercial in confidence. It is the responsibility of the manufacturer to communicate details of the discount to the relevant NHS organisations. Any enquiries from NHS organisations about the patient access scheme should be directed to onccommercial.bra@boehringer-ingelheim.com.
- NICE has developed a costing statement (see also the "Availability of Companion Documents" field) explaining the resource impact of this guidance to help organisations put this guidance into practice.

## Implementation Tools

Mobile Device Resources

Patient Resources

Resources

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

# Institute of Medicine (IOM) National Healthcare Quality Report Categories

## IOM Care Need

Getting Better

Living with Illness

## IOM Domain

Effectiveness

Patient-centeredness

# Identifying Information and Availability

## Bibliographic Source(s)

## Bibliographic Source(s)

National Institute for Health and Care Excellence. Afatinib for treating epidermal growth factor receptor mutation-positive locally advanced or metastatic non-small-cell lung cancer. London (UK): National Institute for Health and Care Excellence; 2014 Apr. 40 p. (Technology appraisal guidance; no. 310).

## Adaptation

Not applicable: The guideline was not adapted from another source.

## Date Released

2014 Apr

## Guideline Developer(s)

National Institute for Health and Care Excellence (NICE) - National Government Agency [Non-U.S.]

## Source(s) of Funding

National Institute for Health and Care Excellence (NICE)

## Guideline Committee

Appraisal Committee

## Composition of Group That Authored the Guideline

*Committee Members*: Dr Lindsay Smith (*Chair*), General Practitioner, West Coker Surgery, Somerset; Dr Andrew Black (*Vice Chair*), General Practitioner, Mortimer Medical Practice, Herefordshire; Professor David Bowen, Consultant Haematologist, Leeds Teaching Hospitals NHS Trust; Dr Ian Davidson, Lecturer in Rehabilitation, University of Manchester; Professor Simon Dixon, Professor of Health Economics, University of Sheffield; Dr Martin Duerden, Assistant Medical Director, Betsi Cadwaladr University Health Board, North Wales; Dr Alexander Dyker, Consultant Physician, Wolfson Unit of Clinical Pharmacology, University of Newcastle; Gillian Ells, Prescribing Advisor – Commissioning, NHS Hastings and Rother and NHS East Sussex Downs and Weald; Professor Paula Ghaneh, Professor and Honorary Consultant Surgeon, University of Liverpool; Professor Carol Haigh, Professor in Nursing, Manchester Metropolitan University; Dr Paul Hepple, General Practitioner, Muirhouse Medical Group; Professor John Hutton, Professor of Health Economics, University of York; Professor Steven Julious, Professor in Medical Statistics, University of Sheffield; Dr Tim Kinnaird, Lead Interventional Cardiologist, University Hospital of Wales, Cardiff; Dr Warren Linley, Senior Research Fellow, Centre for Health Economics and Medicines Evaluation, Bangor University; Dr Malcolm Oswald, Lay member; Professor Femi Oyebode, Professor of Psychiatry and Consultant Psychiatrist, The National Centre for Mental Health; Dr John Radford, Director of Public Health, Rotherham Primary Care Trust and MBC; Dr Murray Smith, Associate Professor in Social Research in Medicines and Health, University of Nottingham

## Financial Disclosures/Conflicts of Interest

Committee members are asked to declare any interests in the technology to be appraised. If it is considered there is a conflict of interest, the member is excluded from participating further in that appraisal.

## Guideline Status

This is the current release of the guideline.

This guideline meets NGC's 2013 (revised) inclusion criteria.

## Guideline Availability

Electronic copies: Available from the National Institute for Health and Care Excellence (NICE) Web site .

## Availability of Companion Documents

The following are available:

- Lung cancer - afatinib. Costing statement. London (UK): National Institute for Health and Care Excellence (NICE); 2014 Apr. 1 p. (Technology appraisal guidance; no. 310). Electronic copies: Available from the National Institute for Health and Care Excellence (NICE) Web site .
- Fleeman N, Bagust A, Beale S, Dwan K, Boland A, Greenhalgh J, Dundar Y, Richardson M, McEntee J, Marshall E. Afatinib for treating epidermal growth factor receptor mutation positive locally advanced or metastatic non-small cell lung cancer. Liverpool (UK): LRiG, University of Liverpool; 2013 Dec. 121 p. Electronic copies: Available in Portable Document Format (PDF) from the NICE Web site .

## Patient Resources

The following is available:

- Afatinib for treating locally advanced or metastatic non-small-cell lung cancer. Information for the public. London (UK): National Institute for Health and Care Excellence (NICE); 2014 Apr. (Technology appraisal guidance; no. 310). Electronic copies: Available from the National Institute for Health and Care Excellence (NICE) Web site . Also available for download as an eBook or ePub from the NICE Web site .

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

## NGC Status

This NGC summary was completed by ECRI Institute on June 29, 2014.

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